FDA Opioids Communications Project
General Population & Family/Friends Screening Questionnaire [phone]

Initial telephone screening script:

Introduction

Hello, my name is _____and I'm calling from the research firm called itracks. I'm calling on behalf of RTI International, an independent, non-profit research organization, about a study being sponsored by the U.S. Food and Drug Administration, or FDA. RTI International will be conducting a series of online video focus groups about prescription pain medications. The focus group will last about 90 minutes and you will receive 75 e-reward points in appreciation for your time. We will take every precaution to protect your privacy. Participants will be asked not to share any information outside of the group and no one outside of itracks will have your personal information. The discussion will be video-recorded and transcribed, but we will not include your name or other identifying information in the transcription or project report.

To see if you are eligible to participate in this research study, I need to ask you a few questions. All of your responses will be kept private.

May I proceed?

Yes ➔ CONTINUE

No ➔ END [Thank respondent and end call.]

1. How old were you on your last birthday?

_____	**Over Age 18 ➔ CONTINUE** **Under Age 18➔ TERMINATE**
SCREEN FOR A MIX OF AGES	

2. Are you a medical or health professional?

Yes		**➔ TERMINATE**
No		**➔ CONTINUE**

3. Have you ever worked for…? [Read the options below]

Department of Health and Human Services		➔ **TERMINATE**
U.S. Food and Drug Administration		➔ **TERMINATE**
Pharmaceutical company		➔ **TERMINATE**
itracks		➔ **TERMINATE**
RTI International		➔ **TERMINATE**
None of the above		➔ **CONTINUE**

4. Have you ever been prescribed any of the following opioids to manage non-cancer pain? [Read options below and record yes or no for each]

	Yes	**No**
Alfentanil (Alfenta)		
Buprenorphine (Belbuca, Bunavail, Buprenex, Butrans, Suboxone, Zubsolv)		
butorphanol		
Codeine (Fioricet w/ codeine, Fiorinal w/ codeine, Tylenol w/ codeine)		
Dihydrocodeine (Synalgos-DC)		
Fentanyl (Abstral, Actiq, Duragesic, Fentora, Ionsys, Lazanda, Sublimaze, Subsys)		
Hydrocodone (Anexsia, Hysingla ER, Lortab, Norco, Reprexain, Vicodin, Vicoprofen, Zohydro ER)		

Hydromorphone (Dilaudid, Dilaudid-HP, Exalgo)		
Meperidine (Demerol) Methadone (Dolophine, Methadose)		
Morphine (Astramorph PF, Duramorph PF, Embeda, Infumorph, Kadian, Morphabond, MS Contin)		
oxycodone (Oxaydo, Oxycet, Oxycontin, Percocet, Percodan, Roxicet, Roxicodone, Xartemis XR)		
oxymorphone (Opana, Opana ER)		
pentazocine (Talwin)		
remifentanil (Ultiva)		
sufentanil (Sufenta)		
tapentadol (Nucynta, Nucynta ER)		
tramadol (Conzip, Ultracet, Ultram, Ultram ER)		

Yes (to one or more)		➔ **CONTINUE TO Q5**
No		➔ **CONTINUE [ASK Q5A]**

5. Have you been taking [DRUGS FROM Q4 THAT R SAYS YES TO] on a regular basis for the **past three (or more) months** to treat your non-cancer pain? By regular, I mean daily or on most days.

Yes		➔ **TERMINATE**
No		➔ **CONTINUE [ASK Q5A]**

5a. Do you have a family member or close friend who has been prescribed any of the following opioids on a regular basis for the **past three (or more) months** to treat non-cancer pain? By regular, I mean daily or on most days.

	Yes	**No**
Alfentanil (Alfenta)		
Buprenorphine (Belbuca, Bunavail, Buprenex, Butrans, Suboxone, Zubsolv)		
butorphanol		
Codeine (Fioricet w/ codeine, Fiorinal w/ codeine, Tylenol w/ codeine)		
Dihydrocodeine (Synalgos-DC)		
Fentanyl (Abstral, Actiq, Duragesic, Fentora, Ionsys, Lazanda, Sublimaze, Subsys)		
Hydrocodone (Anexsia, Hysingla ER, Lortab, Norco, Reprexain, Vicodin, Vicoprofen, Zohydro ER)		
Hydromorphone (Dilaudid, Dilaudid-HP, Exalgo)		
Meperidine (Demerol)		

Methadone (Dolophine, Methadose)		
Morphine (Astramorph PF, Duramorph PF, Embeda, Infumorph, Kadian, Morphabond, MS Contin)		
oxycodone (Oxaydo, Oxycet, Oxycontin, Percocet, Percodan, Roxicet, Roxicodone, Xartemis XR)		
oxymorphone (Opana, Opana ER)		
pentazocine (Talwin)		
remifentanil (Ultiva)		
sufentanil (Sufenta)		
tapentadol (Nucynta, Nucynta ER)		
tramadol (Conzip, Ultracet, Ultram, Ultram ER)		

Yes		**➔ CONTINUE [FAMILY/FRIEND GROUP]**
No		**➔ CONTINUE [GENERAL CONSUMER GROUP]**

NOTE: 2 GROUPS GENERAL CONSUMERS AND 2 GROUPS OF FAMILY/FRIENDS (Opioid users recruited through separate screener)

6. What is your gender? [Ask only if necessary]

Male		**➔ CONTINUE**
Female		**➔ CONTINUE**
SCREEN FOR APPROXIMATELY ½ OF EACH		

7. Do you live in a rural, suburban, or urban setting?

Rural		**➔ CONTINUE**
Suburban		**➔ CONTINUE**
Urban		**➔ CONTINUE**
SCREEN FOR A MIX		

8. Are you Hispanic or Latino? (Monitor distribution to ensure we have diversity as close to U.S. distribution as possible)

Yes		**➔ CONTINUE**
No		**➔ CONTINUE**
SCREEN FOR A MIX		

9. Which of these groups best describes you? You may answer more than one. (Monitor distribution to ensure we have diversity as close to U.S. distribution as possible).

White		**➔ CONTINUE**
Black / African American		**➔ CONTINUE**
American Indian or Alaskan Native		**➔ CONTINUE**
Asian		**➔ CONTINUE**
Native Hawaiian or Pacific Islander		**➔ CONTINUE**
Other		**➔ CONTINUE**
Two or more races		**➔ CONTINUE**
SCREEN FOR A MIX		

10. In which State of the U.S. do you live?

_____		➔ **CONTINUE**
SCREEN FOR A MIX BASED ON THE FOLLOWING REGIONS: **Northeast: (1)** New England (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont); **(2)** Mid-Atlantic (New Jersey, New York, and Pennsylvania) **South: (1)** South Atlantic (Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, Washington D.C., and West Virginia); **(2)** East South Central (Alabama, Kentucky, Mississippi, and Tennessee); **(3)** West South Central (Arkansas, Louisiana, Oklahoma, and Texas) **Midwest: (1)** East North Central (Illinois, Indiana, Michigan, Ohio, and Wisconsin); (2) West North Central (Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, and South Dakota) **West: (1)** Mountain (Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming); **(2)** Pacific (Alaska, California, Hawaii, Oregon, and Washington)		

11. What is the highest level of education you have attained? (Monitor distribution to ensure we have some lower education participants as close to US distribution as possible)

Less than high school		➔ **CONTINUE**
High school graduate (or GED)		➔ **CONTINUE**
Some college or technical school (No degree)		➔ **CONTINUE**
College graduate (2- or 4-year degree)		➔ **CONTINUE**
Some graduate school (No degree)		➔ **CONTINUE**
Graduate school degree		➔ **CONTINUE**
SCREEN FOR A MIX OF THE FOLLOWING: • 1/3 < some or no HS • 1/3 HS graduate or GED • 1/3 Some college or more **(no more than 2 with graduate degrees)**		

Invitation for Eligible Participants

Thank you for answering all of my questions. We would like to invite you to take part in the study.
The discussion will last up to 90 minutes. This is a study related to public health issues. Your participation will help us better understand the issues that we will discuss. No one will attempt to sell you anything, and no one will call you for other studies as a result of your participation. In appreciation for your time, you will receive 75 e-reward points. This is an important research effort, and we hope that you will be part of it. I also want to remind you that the focus groups will be video and audio-recorded and transcribed. The audio files will be shared only with the project team, including the FDA, but will not include any identifying information.

Can we schedule your attendance?
Yes ➔ CONTINUE
No ➔ [Thank respondent and end call]

OFFER AVAILABLE TIMES BASED ON WHICH GROUP PARTICIPANT IS ELIGIBLE FOR.

NOTE: ONLY ONE PARTICIPANT PER FAMILY SHOULD BE RECRUITED ACROSS THE ENTIRE STUDY

We will be sending you instructions for accessing the focus group so before we end the call, I'd like to confirm your contact information **[Complete Participant Information on last page].**

Finally, we will be sending you two copies of a consent form that includes more information about the research study. You MUST return a signed copy of this consent form in order to participate in the focus group. I can either mail them to you and provide a postage-paid envelope for you to send a signed copy back to us, or I can email them to you and you can either email a scanned copy back to us or fax it to us. Which method do you prefer?

IF MAIL

OK, I will mail you two copies of the consent form. Please read and sign one copy of the consent form and return it to us prior to [DATE OF GROUP]. We will provide a postage-paid envelope for you to send it to us. The other copy is for you to keep. Please remember that we must receive the signed consent form from you in order to participate in the group.

If you have any questions about the information in the consent form, you can contact Lauren McCormack at 919-541-6277 or by email at lmac@rti.org

IF EMAIL

I will send you the consent forms by email to [email address].

Follow-up Email Text

Subject: Online Focus Group about Prescription Pain Medication

Thank you for agreeing to participate in our focus group. In order to be able to participate in the group we must receive a signed copy of this form from you prior to [DATE OF GROUP]. Please keep a copy of the form for your records.

Instructions for Returning the Consent Form

1. You can send a scanned copy of the signed form to monica.grebe@itracks.com.
2. You can fax a signed copy of the form to [FAX # for RECRUITER]

If you have any questions about the information in the consent form, you can contact Lauren McCormack at 919-541-6277 or by email at lmac@rti.org

Follow-up Mail Text

Dear [NAME]:

Thank you for agreeing to participate in the online focus group about prescription pain medications. I have included two copies of the consent form for this study. In order for you to be able to participate, we must receive a signed copy of this form from you before the focus group scheduled on [DATE OF GROUP]. Please return one signed copy of the form in the enclosed postage-paid envelope and keep the second copy for your records.

If you prefer, you can email a scanned copy of the signed form to monica.grebe@itracks.com or you can fax a signed copy to [FAX # for RECRUITER].

If you have any questions about the information in the consent form, you can contact Lauren McCormack at 919-541-6277 or by email at lmac@rti.org

Thank you,

RECRUITER

Closing for Ineligible Participants:

I’m sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

Focus Group Log-In Information (to be sent by email)

Subject: Online Focus Group about Prescription Pain Medication

Dear [FULLNAME]:

Thank you for agreeing to participate in our focus group study. This email includes information on how to join the focus group.

Before the research starts please take a few minutes to test the link below to make sure that you are able to login successfully. You will not be able to join the discussion unless our system shows that you have done this.

You can do the test at any time by logging in and clicking on your project [INCLUDE NAME OF LINK]. Our system will check to make sure that everything is working properly. If you have issues doing your check you can call the itracks help desk at any time at 1-888-525-5026 ext. 2 during the week, ext. 7 on weekends.

You will also need to call in by phone for the audio portion of the focus group. This information will be shown to when you log in at the time of the focus group.

The **focus group is scheduled for 90 minutes**, so please be sure to allocate enough time in your schedule to accommodate the entire session.

The details below are what you need to login. When you log in for the first time, you will be asked to create a password. Be sure to write it down so that you do not forget it. After the initial registration, you must enter your Email Address and Project ID exactly as shown to access the session.

Thank you and we look forward to your participation!

Project Date & Time: **[STARTDATE]**
Email Address: **[EMAIL]**
Password: **(you create this the first time you log in)**
Project ID: **[PROJECTSUPPORTID]**
Login Page URL: **[LOGINURL]**

If you have any questions regarding this, please feel free to reply to this email.

Confirmation Call

Hello this is [NAME] calling from itracks regarding an online focus group you recently agreed to participate in.

I'm calling to make sure you received the instructions for logging into the focus group that we sent by email and that you are still willing to participate.

Have you received the instructions? [Wait for answer]

IF NO – Note in sheet and tell participant you will re-send.

And are you still planning on participating? [Wait for answer]

IF NO: Do you have a specific question or concern that I can address about the study? [IF NOT THANKK PARTICIPANT FOR THEIR TIME]

IF YES:

[CHECK TO SEE IF CONSENT FORM WAS RECEIVED. IF NOT REMIND PARTICIPANT TO SEND SAYING: I see you haven't returned a signed copy of the consent form to participate. Please send us that [in the postage-paid envelope provide before your focus group or by email or fax]. You will not be able to participate in the study if we don't receive it.

Ending:

Great. Do you have any other questions at this time?

Thank you [NAME]. We appreciate your participation in this study.

Reminder Call: Consent

Initial reminder call to be made 3 days after the consent is sent if by email, 1 week if by mail. Additional follow-up calls to be made one day after the participant said they would send it.

After two reminder calls and/or 3 days prior to group itracks and RTI will discuss whether to replace participant.

Hello this is [NAME] calling from itracks regarding an online focus group about prescription pain medications that you recently agreed to participate in.

I'm calling because we have not received a signed copy of the study consent form yet. You will not be able to participate in the focus group unless we receive it before the group is scheduled on [DATE OF GROUP].

Are you still planning to participate in the group?

IF NO: Do you have a specific question or concern that I can address about the study? [IF NOT THANK PARTICIPANT FOR THEIR TIME]

IF YES:

Will you be able to return it to us today? [IF NOT, ASK WHEN]. Will you be mailing it, sending it by email, or fax?

Great, I will make a note of when we can expect it.

Thank you [NAME]. We appreciate your participation in this study.

Reminder Calls

If participant has not logged in for the group 10 minutes prior to the start time.

When calling out to someone for reminders:

Hello this is [NAME] calling from itracks regarding the online study you recently agreed to participate in. We noticed you have not logged in yet and wanted to check in to see if you were still planning on participating. With studies like this it is important we get the opinions of everyone selected to participate so we can get many different views on the issue. There is still time for you to participate. Are you still able to join us?

IF YES – confirm and thank

Ending:

IF YES - We will look for you in the study. Any questions at this time?
IF NO – Well, thank you for your time.

Participant Information (screener to collect on initial screening call)

NAME: _____

ADDRESS: _____

CITY: _____

ZIP CODE: _____

EMAIL _____

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: _____

BEST PHONE NUMBER: _____

Is there another time and number we can try if we miss you?

ALTERNATE PHONE NUMBER: _____

Recruiter: _____